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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,871	09/18/2003	Jean-Pascal Zambaux	ATMI-657	6762

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/665,871		ZAMBAUX, JEAN-PASCAL	
	<b>Examiner</b>		<b>Art Unit</b>	
	Leslie R. Deak		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-62 is/are pending in the application.
- 4a) Of the above claim(s) 55-62 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-43, 53 and 54 is/are allowed.
- 6) ☒ Claim(s) 9-10, 17-26, 44, 45, 47, 48, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) 11-16, 46, 49 and 52 is/are objected to.
- 8) ☒ Claim(s) 55-62 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 August 2006 has been entered.
2. Applicant authorized an Examiner's Amendment to the claims on 24 October 2006 in order to pass the case to issue. Upon further evaluation, however, Examiner has determined that the case is not ready for allowance. As such, no Examiner's Amendment has been made to the claims. The claims are pending as filed by Applicant on 18 August 2006.

### ***Election/Restrictions***

3. Newly submitted claims 55-62 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claimed method does not recite all the elements of the claimed device, indicating that the method may be performed with a materially different device. In particular, the claimed device comprises features claimed in the alternative that are not present in the claimed method, and the method claims present limitations that are not recited in the device claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55-26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 9, 10, 17, 19-26, 44, 45, 47, 48, 50, 51 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,122,129 to Olson et al.

In the specification and figures, Olson discloses the apparatus as claimed by applicant. With regard to claims 9, 17, 18, 21, Olson discloses a sampler device designed to preserve the integrity of the sample collected. The apparatus comprises a needle-shaped hollow connector or delivery tube 20 that passes fluids therethrough, an inlet end 13 and an outlet end 21, wherein the inlet end 13 may comprise a threaded connector 19 that connects to container 33 via tube 36 (see FIGS 1, 2, 4, column 6). The outlet end 21 has an aperture to allow fluids to exit into container 23 (see column 7, lines 1-35). The connector comprises a membrane or drip boot 22 (see FIG 4). Absent the disclosure that the drip boot or membrane comprises a vacuum, there is gas

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inherently contained within the membrane. Furthermore, Olson teaches that the entire assembly is sterile (see column 1, lines 5-12, column 2, lines 20-25) to prevent contamination of the sample obtained through the connector 21, indicating that the gas within the membrane is sterile.

Applicant further claims that the connector comprises **one of** i) a particular pressure of the gas in the membrane, ii) a partial slit in the membrane, iii) a latch between the container and the connector, or iv) a threaded connection between the connector and the container. Olson illustrates a threaded connection 19/30 between the connector and the container via tube 36 (see FIGS 3, 4). Examiner further interprets applicant's claim drawn to a latch between the container and connector to be a broad recitation of the threaded connection pointed out above. Since Olson discloses two of the four features claimed by applicant in the alternative, the Olson disclosure meets the limitations of the claims.

With regard to claim 10, it is the position of the examiner that gas, comprising atmospheric air, is contained within the chamber disclosed by Olson, since Olson does not disclose the chamber as comprising a vacuum. Since atmospheric air comprises a mixture of oxygen and nitrogen, the disclosure meets the limitations of the claims.

With regard to claims 19, 20, 51 Olson illustrates a needle-shaped cannula 21 as the connector and a flexible bag 33 as the container (see FIGS 1, 4).

With regard to claim 22, Olson discloses and illustrates that the outlet end of the connector 21 may engage a conventional vacuum tube 23 for receiving fluids through the connector (see FIGS 1, 6, column 7, lines 1-37).

With regard to claims 23-26, Olson discloses that the device may be used to collect blood, which includes whole blood and various blood components, meeting the limitations of the claims (see column 6, lines 18-25).

With regard to claim 44, Olson specifically discloses a kit with the claimed device including packaging materials (see FIG 8, column 5, lines 19-23). Olson does not disclose instructions or indicia on or inside the packaging material. However, applicant has not disclosed or claimed any functional relationship between the components in the kit and the printed matter. The lack of a functional relationship between the kit components and the kit render the instantly claimed kit unpatentable over the prior art of record. See In re Ngai, 70 USPQ2d 1862 (Fed. Cir. 2004). In the instant case, the printed matter, although it may recite a method of using the kit, does not depend on the kit, and the use of the kit does not depend on the printed matter. Therefore, the Olson disclosure meets the limitations of the claims.

With regard to claim 45, Olson discloses a fluid 34 within container 33 (see FIG 1).

With regard to claims 47 and 50, Olson illustrates a threaded connection 19/30 between the connector and the container via tube 36 (see FIGS 3, 4). Examiner interprets applicant's claim drawn to a latch between the container and connector to be a broad recitation of the threaded connection pointed out above.

With regard to claim 48, Olson illustrates the hollow connector 21 as a piercing element (see FIG 4).

***Allowable Subject Matter***

6. Claims 27-43 and 53-54 are allowed.
7. The following is an examiner's statement of reasons for allowance: The prior art fails to disclose or suggest the device claimed by applicant. In particular, the prior art fails to disclose or suggest the connector claimed by applicant with a membrane over the hollow connector creating a chamber with a gas contained therein, wherein the gas has a pressure of greater than 1atm inside the chamber, along with the other steps and limitations of the claims
8. Claims 11-16, 46, 49, and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. The following is an examiner's statement of reasons for allowance: The prior art fails to disclose or suggest the device claimed by applicant. In particular, the prior art fails to disclose or suggest the connector claimed by applicant with a membrane over the hollow connector creating a chamber with a gas contained therein, wherein the gas has a particular sterility, has a claimed pressure inside the chamber, or the membrane has a particular thickness or partial slit, along with the other steps and limitations of the claims

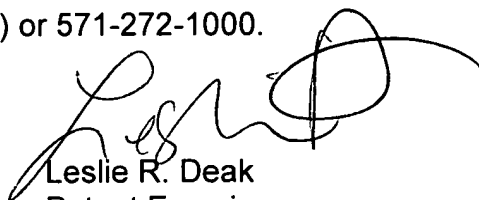
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
8 November 2006

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

